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(54) SYSTEM FOR HEMODYNAMIC PACING IN VENTRICULAR TACHYCARDIA

VORRICHTUNG ZUR HÄMODYNAMISCHEN STIMULATION BEI EINER VENTRIKULÄREN TACHYKARDIE

SYSTEME DE REGULATION HEMODYNAMIQUE EN CAS DE TACHYCARDIE VENTRICULAIRE

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(73) Proprietor: **MEDTRONIC, INC.**
Minneapolis, Minnesota 55432 (US)

(72) Inventor: **WITTKAMPF, Frederik, H., M.**
NL-3723 DW Bilthoven (NL)

(74) Representative: **Hughes, Andrea Michelle**
Frank B. Dehn & Co.,
European Patent Attorneys,
179 Queen Victoria Street
London EC4V 4EL (GB)

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- **MEDICAL AND BIOLOGICAL ENGINEERING, vol. 10, 1972, pages 297-300, XP000611358 M. MERX ET AL.: "A TRIGGERED GENERATOR FOR THE ELECTRICAL TREATMENT OF TACHYCARDIAS" cited in the application**
- **IEEE ENGINEERING IN MEDICINE AND BIOLOGY MAGAZINE, vol. 9, no. 2, 1 June 1990, pages 36-39, XP000173569 WILKOFF B L ET AL: "TACHYCARDIA CONTROL WITH CARDIAC PACEMAKERS"**

EP 0 862 484 B1

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Description

[0001] This invention relates to a pacing apparatus for controlling the effect of ventricular tachycardia (VT) and, more particularly, a system for delivering a specific pacing therapy when VT is detected.

[0002] Ventricular tachycardia is a subject that has been widely investigated, and different therapies have been proposed. It is known in the art to provide specific pacing therapies for trying to control or suppress VT. Such pacing therapy is preferably applied by a device which includes an automatic defibrillator and a pacemaker, so that back-up therapies are available. While certain therapies have been noted to achieve a certain success in controlling VT, it remains an area where significant improvement is desired. Uncontrolled VT can, as is known, lead to ventricular fibrillation (VF), which even when treated imposes a serious trauma and consequence on the patient.

[0003] In another environment, namely a catheterization lab, there occurs a circumstance of investigating the focus of a patient tachycardia, usually in the left ventricle. In this circumstance, it is actually desirable not to suppress the tachycardia, since the VT should be maintained in order to complete the investigation. However, it is also very desirable to improve cardiac output so that the patient can tolerate the procedure. There is thus an additional need to provide a therapy applicable in this circumstance, to enhance the patient condition during VT and prevent the patient from slipping into VF.

[0004] It has been observed that in some patients with VT or supraventricular VT, the arterial pressure waves often show a 1:2 ratio with the underlying electrical rhythm of the heart. This situation occurs spontaneously in some patients, and the hemodynamic response to stable VT may vary between a 1:1 and a 1:2 response, with a relatively slow and gradual alternation between these responses. This can be observed during electrophysiological studies when arterial pressure is monitored together with the ECG. It is also possible that a 1:2 response can be induced by a single extra stimulus that is delivered, as during electrophysiological studies. Such a 1:2 hemodynamic response which is induced in this way often disappears gradually within five to ten beats after initiation. Of importance is the observation that such alternating arterial pressure waves may provide significant increase in cardiac output, and relief to the patient, even though the VT continues.

[0005] In 1972 Irnich and coworkers described a 1:2 pacing algorithm in patients with various tachyrhythmias. See "A Triggered Generator For the Electrical Treatment of Tachycardias," *Med. and Biol. Eng.* 10, pp. 297-300, Pergamon Press, 1972. Single extra stimuli with short coupling intervals, i.e., short intervals following the last tachy beat, were delivered to induce alternating arterial pressure waves. The short interval results in a decreased filling of the ventricles and low systolic pressure, while the longer duration of the next diastolic interval that follows causes an increased end-diastolic volume and a higher end-systolic pressure. The coupling disclosed in the referenced paper is relatively short, in the range of about 150 to 250 ms. In fact, the purpose was to deliver the extra stimulus as early as possible after the termination of the ventricular refractory period. However, pacing with very short coupling intervals relative to the preceding spontaneous beats has the potential to change the tachycardia in a dangerous manner. While the referenced paper reports that the extra stimulus sometimes terminated the tachycardia, it also has the potential to change the tachycardia into another and more dangerous type. It is my observation that any therapy which seeks to realize the benefit of 1:2 pacing must be programmed to avoid interrupting the tachycardia; anti-tachyrhythmia pacing, due to its potential for danger, should only be undertaken in conjunction with a defibrillator, and in any event not in an implantable pacemaker with no defibrillation backup. There thus is a need to provide a safer, and yet efficient pacing therapy, with a reduced potential to change the tachycardia into a more dangerous type and otherwise distort the recovery from tachycardia.

[0006] It is my observation that very short coupling intervals are not necessary to obtain a hemodynamic 1:2 response. Specifically, it is my observation that only slight variations in cycle length are required to induce the benefit of 1:2 pacing, namely increasing amplitude of alternate arterial pressure waves. Since most VTs have a circuit or focus that is located in the left ventricle, and since the pacing stimulating electrode is positioned in the right ventricle, the distance from the electrode to the source of tachycardia is relatively large. This means that a stimulus that is delivered shortly before the expected spontaneously occurring depolarization will not interfere with the VT mechanism.

[0007] Accordingly, the basis of the subject invention is to provide 1:2 pacing as a response to VT, with a timing of the alternate stimulus being such that every second-beat is advanced only slightly, preferably on the order of 40-60 ms relative to the expected timing of the next beat. A stimulus delivered less than 30 milliseconds before the expected next beat would have no effect; and a stimulus more than about 125-150 ms early could be dangerous. The timing of the stimulus should be adjusted to the cycle length of the tachycardia, so that the advancement (Δ) is a time interval independent of the tachy rate. By coupling the stimulus to the next expected next beat, as opposed to the last beat, and keeping the advancement relatively small, the benefit of the therapy is obtained without risking interruption of the tachycardia.

[0008] It is an object of this invention to provide a system for providing a hemodynamic pacing therapy in response to ventricular tachycardia, the therapy giving the benefit of increased arterial pressure while avoiding the danger of invoking a more dangerous form of VT, or VF.

[0009] Accordingly, the present invention provides an implantable cardiac pacing system, having a controllable pulse generator for generating pacing pulses and a lead for delivering pacing pulses to a patient's ventricle and for sensing natural heartbeats in said patient's ventricle, VT means for detecting when said patient is in ventricular tachycardia, response means for responding to detected VT by controlling said pulse generator to deliver pace pulses in a 1:2 relation to the patient's natural cardiac rhythm during said VT, said response means having:

> measure means for determining a measure of the patient's natural rhythmic interval (T) during said VT;
> determining means operative after a sensed natural heartbeat for determining, based on said measure of T, a time of expected occurrence of the patient's next natural heartbeat; and
> control means for controlling said pulse generator to generate a pacing pulse following a ventricular sense and before the said next expected natural heartbeat, said pacing pulse to precede said next expected heartbeat by a predetermined time greater than 30 ms and less than 150 ms.

[0010] The objects of the invention are thus met by controlling the delivery of a stimulus pulse every second beat during stable VT, the stimulus pulse being timed in relation to the next expected natural beat, and preceding such next expected natural beat by only a short time duration which is in the range of 30-150 ms. The preferred system provides for monitoring changes in the VT rate during the 1:2 pacing, and for adjusting the timing or exiting the pacing therapy when certain differences in the natural rate are detected, i.e., the tachy is not stable. The pacing therapy of this invention provides an improved hemodynamic performance during VT, which in turn enables a longer period of relative comfort for the patient, and which results in reduction in the number of VF episodes. The improved hemodynamic performance enables a longer period during which alternate anti-tachycardia pacing attempts can be attempted under appropriate circumstances, and is of great benefit to the patient during procedures such as catheter mapping.

[0011] Preferred embodiments will now be described by way of example only, with reference to the accompanying drawings.

[0012] Fig. 1 is a block diagram of an overall system according to the invention, showing the environment in which the pacemaker operates.

[0013] Fig. 2 is a block diagram which illustrates basic components of a pacemaker according to this invention, together with leads and a sensor for delivering signals to and/or receiving signals from the patient.

[0014] Fig. 3 is a flow diagram showing the primary sequential steps carried out cyclically by a pacemaker according to this invention, limited to the steps taken in performing the 1:2 pacing during VT, in accordance with the system of this invention.

[0015] Fig. 4 is a timing diagram which illustrates the operation of the pacing algorithm of this invention during a condition of ventricular tachycardia.

[0016] The system of this invention is based upon a device capable of providing a specific pacing therapy in response to VT. Although the system is illustrated in terms of a pacemaker which provides a pacing response, it is noted that such a pacemaker is preferably incorporated as part of a larger system capable of delivering defibrillation therapy in the event that the patient goes into ventricular fibrillation. Also, it may be combined with a system that can be programmed to provide an alternative form of anti-tachycardia therapy.

[0017] The system of this invention is preferably software-based, i.e., the software controls functions through hardware, as illustrated in Fig. 1. Referring specifically to Fig. 1, the pacemaker portion 50 of the device of this invention is shown as having a component hardware portion 51 and a software portion 52, the two portions being interconnected. The software is parameter-driven, i.e., there are numerous parameters that control the pacing behavior, diagnostic functions, etc. The hardware is interconnected with the patient's heart by one or more electrodes 55, and one or more sensor connections 54. As is well understood in the art, for a dual chamber pacemaker, there are generally two leads, an atrial lead and a ventricular lead, each lead having at least one electrode, unipole or bipole, positioned in the heart. The line 54 is illustrated as leading to the heart, as in a QT-type sensor arrangement, but may be attached to the outside case of the pacemaker or may couple to any other available sensors for sensing body parameter information used in rate responsive pacing systems.

[0018] As further illustrated in Fig. 1, the pacer 50 is in telemetric communication with a programmer 56. The user can select parameters and program them through programmer 56, and can also interrogate parameter and diagnostic data from the implanted pacemaker. Interrogated information from the pacer can be coupled by telemetry directly to a printer 58. Input/output devices 57 are used to input information by the user to the programmer, or to display information received by the programmer from the pacemaker.

[0019] Referring to Fig. 2, there is shown a basic block diagram of primary hardware components of a DDDR pacer 50. Although the subject invention is limited to ventricular pacing, a dual chamber DDDR pacer is illustrated, since the invention could be practiced with a single chamber pacemaker portion, or a programmable dual chamber portion. An atrial generator 61 is shown, having an output connected to lead 62 which communicates with the patient's atrium. An A-sense amplifier 65 is illustrated also connected to atrial lead 62. A ventricular generator is illustrated which is connected to the patient's ventricle through lead 64. V-sense amplifier 66 is also connected to lead 64, to receive and sense signals from the patient's ventricle. Generators 61 and 63 and sense blocks 65 and 66 are interconnected with microprocessor system 60, which microprocessor has software which is parameter-driven to control the operation of the hardware units. Microprocessor system 60 may be interconnected with hardware logic and/or timing circuits 68. As affects the scope of this invention, the degree to which software supplants hardware, or vice versa, is a matter of design choice. Thus, for the many timing functions that are carried out in the pacing system of this invention, it is to be understood that the microprocessor may have built in timing circuits, or suitably may control external hardware timer circuits. Software control of pacing function, and specifically setting the ventricular escape interval (V_{esc}), is well known in the art, such that the following detailed discussions of a preferred software routine enables one of ordinary skill in this art area to design a system for carrying out the functions within the scope of the invention. Data inputted from programmer 56 is stored in memory associated with microprocessor. A sensor S may also be used for providing rate information if the device is to be used as a rate responsive pacemaker.

[0020] Referring now to Fig. 3, there is shown a flow diagram which is limited to illustrating the primary steps taken cyclically by a pacemaker incorporating the features of this invention, in order to set V_{esc} so as to control ventricular pacing during VT. The routine is preferably run under the control of microprocessor 60. At block 70, a determination is made as to whether or not there is a condition of ventricular tachycardia (VT). Techniques for determining VT are well known in the art, and the criteria for detecting onset of tachycardia can be programmed by one of ordinary skill in the art utilizing a conventional programmer as illustrated at 56 in Fig. 1. The determination of VT includes getting a measure of T, the tachycardia cycle length. If it is determined that there is no VT, the device can be programmed to remain quiescent, i.e., deliver no pace pulses until a VT is detected. Alternatively, the device can act as a conventional pacemaker, in which case handling of the ventricular event is done in the conventional manner. Thus, when the patient is without VT, the pacer sets V_{esc} and waits to see whether it times out or whether a V_{sense} intervenes. When there has been a time out, the pacemaker delivers a ventricular pace pulse (VP) and resets V_{esc}; if a V_{sense} has been determined, no VP is delivered, and the pacemaker simply resets V_{esc}.

[0021] Returning to block 70, if VT has been detected, the routine proceeds to block 72, and sets V_{esc} to the value of T-D , where Δ is a programmed constant and reflects the advance before the next expected tachy beat when a pulse is to be delivered early. In other words, for a tachy with a substantially constant T, every other cycle the pacer will try to deliver a stimulus pulse at a time Δ before the tachy beat would otherwise occur. After V_{esc} is set, the pacemaker waits to see if it times out, or whether time out is preceded by a sensed ventricular beat, V_{sense}. At 74, the next event is examined to see if it was a time out. If no, this means that there was a V_{sense} before time out, as seen at (1) in Figure 4. In this event, the routine exits, since the tachy is not stable enough for effective 1:2 pacing therapy. However, if the event was a time out, the pacemaker delivers a V stimulus, as seen at block 75.

[0022] Following delivery of a stimulus, the routine resets V_{esc}, as seen at block 80. The V_{esc} is set to a value of $T + \Delta + d$, where d is a predetermined value representative of the maximum tolerated variation in T. The pacemaker then waits for the next event. Upon occurrence of the next event, it is determined at 82 whether there has been a time out of the escape interval. If yes, this means that no sense has been detected, such that the next sense is going to be after $T + \Delta + d$, as illustrated at (2) in Figure 4. This indicates that the tachy is slowing down, and it is preferable not to deliver a stimulus pulse. Accordingly, the routine exits. However, if there has not been a time out, the routine goes to 84 and determines whether the sense has occurred before $T + \Delta - d$, as illustrated at (3) in Figure 4. If yes, the tachy has increased, or accelerated, and it is preferred not to remain in this 1:2 routine. The pacemaker can adjust the routine, such as by varying Δ or d, as shown at 85, or just exit the routine. However, if the answer at 84 is no, the routine goes to block 86 and updates the value of T. This is preferably done by timing the period between V_{sense} events, i.e., senses before and after a V stimulus, and dividing by 2. The routine then loops back to 72, and sets the escape interval to deliver a next early pace pulse.

[0023] It is seen that for a substantially stable VT, the routine of Figure 3 provides delivery of a pace pulse every other cycle, or 1:2 pacing; each delivered pulse is advanced in time relative to the expected next natural ventricular beat, giving rise to the beneficial increasing arterial pressure. At the same time, this pacing mode is not continued if either a rapidly increasing or decreasing VT is detected, i.e., the tachy is not substantially stable. By timing the 1:2 pacing with respect to the next expected beat, and limiting the Δ advance to about 30-150 ms, and preferably 30-90 ms, the pacing does not interrupt the tachycardia, but it improves the hemodynamic performance and lessens the likelihood of ventricular fibrillation.

Claims

1. An implantable cardiac pacing system, having a controllable pulse generator (63) for generating pacing pulses and a lead (64) for delivering pacing pulses to a patient's ventricle and for sensing natural heartbeats in said patient's ventricle, VT means (66) for detecting when said patient is in ventricular tachycardia, response means (60) for responding to detected VT by controlling said pulse generator to deliver pace pulses in a 1:2 relation to the patient's natural cardiac rhythm during said VT, said

response means having:

measure means for determining a measure of the patient's natural rhythmic interval (T) during said VT;
determining means operative after a sensed natural heartbeat for determining, based on said measure of T, a time of expected occurrence of the patient's next natural heartbeat; and
control means for controlling said pulse generator to generate a pacing pulse following a ventricular sense and before the said next expected natural heartbeat, said pacing pulse to precede said next expected heartbeat by a predetermined time greater than 30 ms and less than 150 ms.

2. The pacing system as described in claim 1, wherein said predetermined time is in the range of 40-60 ms.

3. The pacing system as described in claim 1, wherein said predetermined time is greater than about 50 ms.

4. The pacing system as described in any preceding claim, wherein said measure means comprises means for determining the time interval between the natural beat preceding a delivered pacing pulse and the natural beat following said delivered pacing pulse.

5. The pacing system as described in any preceding claim, comprising means for adjusting said predetermined time.

6. The pacing system as described in any preceding claim, comprising tachy change means for determining when the patient VT has changed by more than a predetermined tolerance, and adjust means for adjusting the response of said response means when VT is determined to have changed by more than said tolerance.

Patentansprüche

1. Implantierbares Herzschrittmachersystem, mit einem steuerbaren bzw. regelbaren Impulsgenerator (63) für die Erzeugung von Schrittmacherimpulsen, einer Leitung (64) für die Lieferung der Schrittmacherimpulse an einen Ventrikel eines Patienten und für die Erfassung natürlicher Herzschläge im Ventrikel des Patienten, VT-Mitteln (66), die erfassen, wenn sich der Patient in einer ventrikulären Tachykardie befindet, sowie Antwortmitteln (60), die auf die erfaßte VT durch Steuern bzw. Regeln des Impulsgenerators antworten, damit er während der VT Schrittmacherimpulse in einer 1:2-Beziehung zu dem natürlichen Herzrhythmus des Patienten liefert, wobei die Antwortmittel aufweisen:

Meßmittel, die einem Meßwert für das natürliche Rhythmusintervall (T) des Patienten während der VT bestimmen;
Bestimmungsmittel, die nach einem erfaßten natürlichen Herzschlag arbeiten, um auf der Grundlage des Meßwertes von T einen Zeitpunkt zu bestimmen, zu dem das Auftreten des nächsten natürlichen Herzschlags des Patienten erwartet wird; und
Steuer- bzw. Regelmittel, die den Impulsgenerator so steuern bzw. regeln, daß er einen Schrittmacherimpuls nach einer ventrikulären Erfassung und vor dem nächsten erwarteten natürlichen Herzschlag erzeugt, wobei der Schrittmacherimpuls dem nächsten erwarteten Herzschlag um eine vorgegebene Zeit vorhergehen soll, die größer als 30 ms und kleiner als 150 ms ist.

2. Schrittmachersystem nach Anspruch 1, bei dem die vorgegebene Zeit im Bereich von 40 bis 60 ms liegt.

3. Schrittmachersystem nach Anspruch 1, bei dem die vorgegebene Zeit größer als etwa 50 ms ist.

4. Schrittmachersystem nach einem der vorhergehenden Ansprüche, bei dem die Meßmittel Mittel umfassen, die das Zeitintervall zwischen dem einem gelieferten Schrittmacherimpuls vorhergehenden natürlichen Schlag und dem dem gelieferten Schrittmacherimpuls folgenden natürlichen Schlag bestimmen.

5. Schrittmachersystem nach einem der vorhergehenden Ansprüche, das Mittel zum Einstellen der vorgegebenen Zeit aufweist.

6. Schrittmachersystem nach einem der vorhergehenden Ansprüche, das Tachy-Änderungsmittel, die bestimmen, wenn sich die VT des Patienten um mehr als eine vorgegebene Toleranz geändert hat, sowie Einstellmittel, die die Antwort der Antwortmittel einstellen, wenn für die VT bestimmt wird, daß sie sich um mehr als die Toleranz geändert hat, aufweist.

Revendications

1. Système de stimulation cardiaque implantable, possédant un générateur d'impulsion contrôlable (63) pour générer des impulsions de stimulation et une sonde (64) pour délivrer des impulsions de stimulation au ventricule d'un patient et pour détecter

les battements de coeur naturels dans ledit ventricule du patient, des moyens de détection de la TV (66) pour détecter quand ledit patient est en tachycardie ventriculaire, des moyens de réponse (60) pour répondre à la TV détectée par la commande dudit générateur d'impulsions pour qu'il délivre des impulsions de stimulation dans un rapport 1/2 au rythme cardiaque naturel du patient pendant ladite TV, lesdits moyens de réponse comprenant:

des moyens de mesure pour déterminer une mesure de l'intervalle rythmique naturel du patient (T) pendant ladite TV ;
des moyens de détermination fonctionnant après un battement de coeur naturel détecté pour déterminer, sur la base de ladite mesure de T, un temps de prévision du prochain battement de coeur naturel du patient ;
et des moyens de commande pour commander ledit générateur d'impulsions pour qu'il génère une impulsion de stimulation après une détection ventriculaire et avant ledit prochain battement naturel prévu, ladite impulsion de stimulation devant précéder ledit prochain battement de coeur prévu par un temps prédéterminé supérieur à 30 ms et inférieur à 150 ms.

2. Système de stimulation selon la revendication 1, dans lequel ledit temps prédéterminé se situe entre 40 et 60 ms.

3. Système de stimulation selon la revendication 1, dans lequel ledit temps prédéterminé est supérieur à 50 ms environ.

4. Système de stimulation selon l'une quelconque des revendications précédentes, dans lequel lesdits moyens de mesure comprennent des moyens de détermination de l'intervalle de temps entre le battement naturel qui précède une impulsion de stimulation délivrée et le battement naturel suivant ladite impulsion de stimulation délivrée.

5. Système de stimulation selon l'une quelconque des revendications précédentes, comprenant des moyens d'ajustement dudit temps prédéterminé.

6. Système de stimulation selon l'une quelconque des revendications précédentes, comprenant des moyens de détection de variation tachycardique pour déterminer quand la variation de la TV du patient a dépassé la tolérance prédéterminée, et des moyens d'ajustement pour ajuster la réponse desdits moyens de réponse lorsque la variation de la TV est déterminée comme ayant dépassé ladite tolérance.

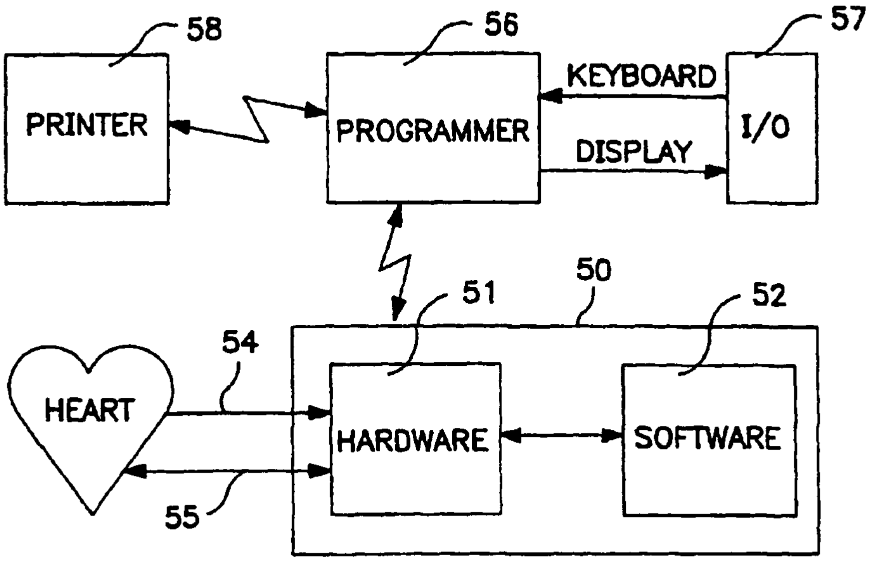
58
PRINTER
56
PROGRAMMER
KEYBOARD
DISPLAY
57
I/O
50
51
52
54
HEART
HARDWARE
SOFTWARE
55

FIG. 1

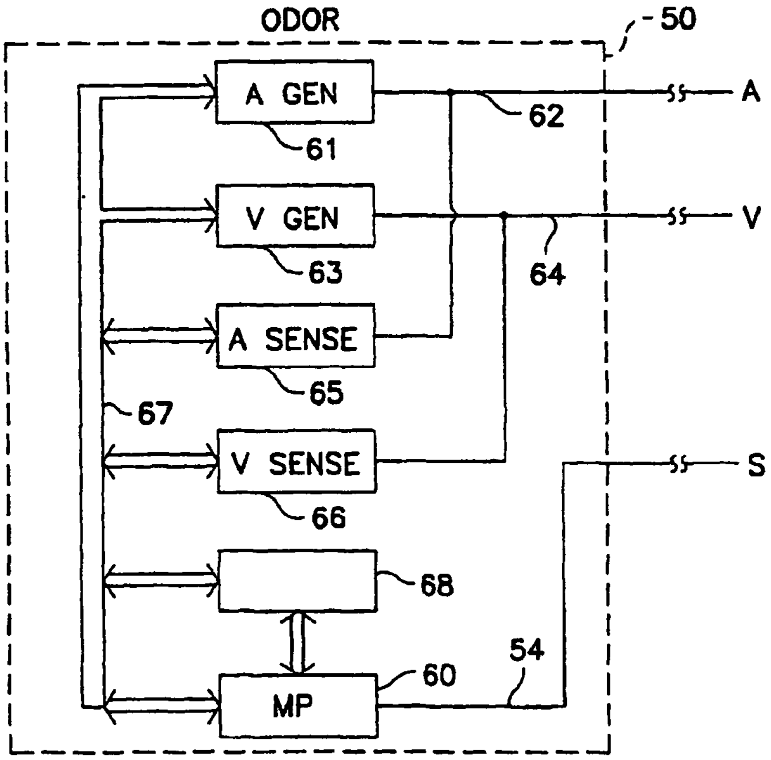
ODOR
50
A GEN
61
62
A
V GEN
63
64
V
A SENSE
65
67
V SENSE
66
S
68
60
54
MP

FIG. 2

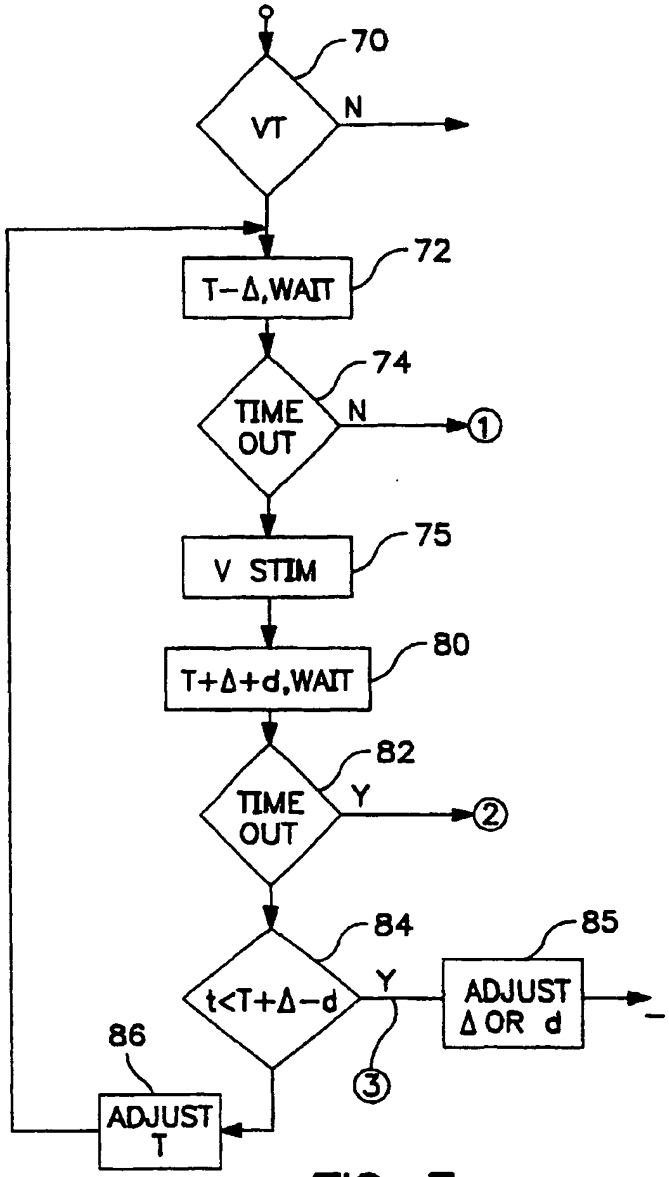
70
VT
N
72
T−Δ, WAIT
74
TIME OUT
N
①
75
V STIM
80
T+Δ+d, WAIT
82
TIME OUT
Y
②
84
t<T+Δ−d
Y
③
85
ADJUST Δ OR d
86
ADJUST T

FIG. 3

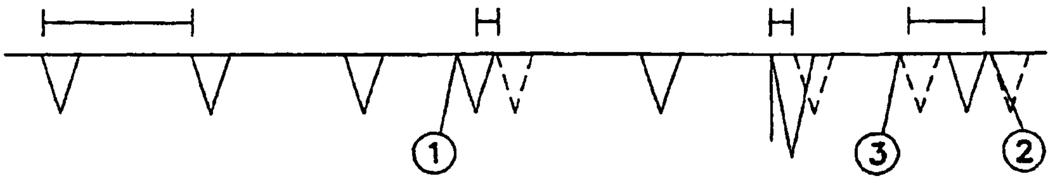
①
③
②

FIG. 4